

REMARKS

Office action summary. Claim 39 is rejected as indefinite for having the same scope as claim 1. Claims 1-41 are rejected as obvious over U.S. Patent No. 4,904,247 (Therriault) in combination with U.S. Patent No. 4,552,751 (Inaba). Claims 1-41 are also rejected over Therriault in combination with U.S. Patent No. 5,800,832 (Tapolsky). Claims 42-59 are rejected over Therriault in combination with Inaba, or Therriault in combination with Tapolsky, further in view of U.S. Patent No. 5,891,453 (Sagel).

Applicants appreciate the withdrawal of the anticipation rejections.

These rejections are overcome by the amendments in this response and otherwise traversed.

Claim amendments. Claim 39 is cancelled in light of the Action's observation that it has the same scope as claim 1. Claims 40-42 are amended to correct dependency in light of the cancellation of claim 1. Claim 60 is added to recite a subset of the list of polymers in claim 8. No new matter is added.

Introductory. The Action states (pp. 4, 7):

Applicants' claim 1 is directed to composition comprising
(1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and
(c) oligomer;
(2) active agent, and
(3) erodible backing.

This is incorrect. The claim, given in the Listing of the Claims, has further limitations. It is improper for the Office to neglect claim limitations whether it be for obviousness or anticipation. "In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety." *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1480-81 (Fed. Cir. 1998).

Obviousness combination of Therriault and Inaba. For the reasons explained in detail in the prior office action response, Inaba teaches away from the use of gels. Therriault on the other hand is concerned with compositions comprising hydrogels (see, e.g., Therriault claim 1) and the present claims also require a hydrogel. The combination of Therriault with Inaba is consequently improper. "It is improper to combine references where the references teach away from their combination." MPEP § 2145.X.D.2. For this reason alone, there is no *prima facie* case of obviousness arising from the combination of Therriault with Inaba.

In addition, the Action does not establish that the combination of Therriault and Inaba produces the invention as claimed, including the limitation that “the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel.” The Action merely claims (p. 6), without reasoning, that “The erosion of the layer that controls the release of the active agent and made of water insoluble polymer is expected to be slower than layer containing water soluble polymers.”

To begin with, the release controlling layer in Inaba is not a backing member as understood by those of skill in the art. In delivery of actives it is well understood that a backing member is one which lies behind the layer in contact with the surface to which the actives are to be delivered, not one which lies between these and the surface and is used to control the rate of drug release. See, e.g., patent application serial no. 10/137,664 at paragraphs [000121] and [000122], distinguishing backing layers from rate-controlling membranes.¹ Inaba, because of its focus on intravaginal suppositories which apparently contact on both sides mucosa to which prostaglandins are to be delivered, does not make use of any backing member, so it is not appropriate to call on Inaba for teachings of a backing member.

What is more, the Action also claims (p. 7) that “Inaba teaches that multilayered film that has different time of erosion of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose.” This contention is not accompanied by any cite to Inaba. As far as the undersigned counsel can determine, Inaba does not say anything about the relative time of erosion of the different layers making up its suppositories, let alone anything about the relation of such relative times of erosion to the “desired long lasting release pattern at a required concentration required for therapeutic purpose.” *Cf.* Inaba claim 1 (“wherein said drug storing layer(s) and drug release controlling layers are formulated so as to dissolve or decompose totally after administration to a mucosal site.”). The Action’s reasoning as to Inaba is therefore not well taken.

Obviousness combination of Therriault and Tapolsky. A rejection under 35 U.S.C. § 103 requires the following analysis: “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and

¹ The cited application published as U.S. Published Patent Application No. 20030170308, where the cited paragraphs are numbered [0161] and [0162]. Priority is claimed to this application in paragraph [0001] of the present application, and it is incorporated by reference in paragraph [000146] of the present application.

the level of ordinary skill in the pertinent art resolved.” *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Then, “the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not” (MPEP § 2142). The Action fails to meet this standard.

The Action, having misstated the content of the claims as indicated above, ignores the limitation “the backing member is comprised of a polymer composition that erodes in a moist environment *at a slower rate than the hydrogel*.” If that limitation were taken into account rather than being ignored, then it would immediately be seen that the combination of references would not result in that which was claimed. As the Action admits (p. 9), there is no teaching of a backing layer in Therriault. Tapolsky does have a teaching of a backing layer, but it is the *exact opposite* of what is taught here: “the adhesive layer . . . will have a slower dissolution time, given that the backing layer protects the interior, adhesive layer and *will dissolve first*.” Tapolsky col. 5, lines 33-36. For this reason alone, the combination of Therriault with Tapolsky does not create a *prima facie* case of patentability.

Combinations in view of Sagel. Because none of the primary references teaches tooth whitening actives, the Action brings in Sagel.

The combinations of references including Sagel are improper for the reasons that the combinations of the primary references are improper as indicated above.

Furthermore, as regards motivation to combine, the Action reasons (p. 12) that “One would have been motivated to [replace the active of Tapolsky with tooth whitening agents chosen from peroxides and metal chlorites] because Sagel teaches that such materials a[re] preferred material for tooth whitening for inclusion in gel strips applied to the muc[o]us membrane.” There are a number of problems here.

The Action’s statement begs the question of what would have motivated a person of skill in the art starting with Tapolsky, Inaba, or Therriault to take an interest in tooth whitening at all. Once you are into tooth whitening, it may make sense to choose your actives based on Sagel’s teaching, given the popularity of the tooth whitening systems sold by the Sagel assignee; but if your starting point is Tapolsky, Inaba, or Therriault, how do you decide on tooth whitening in the first place? While Tapolsky argues that its system can be used with a variety of “pharmaceuticals,” the sole claim of Tapolsky limited to dyclonine HCl, an over-the-counter

anesthetic ingredient. The fact that the claim is so limited casts some doubt on Tapolsky's ability to deliver other actives successfully. There is quite an elaborate laundry list of actives in Tapolsky col. 7, but tooth whiteners do not make the cut. Therriault is likewise agnostic about just what pharmaceutical agent can be delivered. Inaba focuses on prostaglandins (see claim 1).

The Action's reasoning also misstates Sagel's teachings: "the delivery system is placed on the surface of the teeth" (Sagel Abstract), not "applied to the mucous membrane" as the Action states (p. 12). Tooth whitening systems only touch the mucous membranes in the mouth as a side-effect of their use. What is good for mucous membranes is not necessarily good for adhering to the teeth. Furthermore, a good backing member that lasts longer than the adhesive layer, as claimed here, may be designed to shield mucous membranes from the active in the adhesive layer. See paragraph [000137] of the present application and claim 40.

In addition, the Action's statement regarding likelihood of success for the combinations with Sagel (p. 12) is purely conclusory. There is no reasoning to explain why such a likelihood would have been known and expected *at the date of invention* (the date for determining obviousness). The Action merely recites the invention roughly as claimed in claim 1 and then praises it²:

One would reasonably expect formulating laminate wherein one layer comprises hydrophilic composition comprising water swellable water insoluble polymer, water soluble polymer, oligomer, and active agent selected from peroxide or metal chlorite that whiten teeth, and a second layer comprises polymer having slower erosion, wherein the laminate when applied to teeth will whiten the teeth effectively and safely with great success.

This statement relates to what the inventors have discovered, but it does not follow from Tapolsky, Therriault, Inaba or Sagel for the reasons explained above.

Dependent claims. The Action provides no reasoning specific to dependent claims. For example, specific polymers for the backing member are recited in claims 8-16. Of these, the description of the backing layer in Tapolsky (col. 6, lines 33-49) – the only backing layer in the primary references – recites only certain specific cellulose-derived polymers, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, and ethylene oxide-propylene oxide copolymers. As an

² The Examiner's praise of the invention in the quoted text should perhaps be viewed as a secondary consideration favoring nonobviousness.

example, there is no recitation there of “acrylate polymers . . . , starches, alginic acid, alginates, polyamino acids” set out in claim 8, claims 12-16, and new claim 60.

As a further example, claim 40 requires that the backing layer be impermeable to the active agent. The rate controlling membrane of Inaba would not be so impermeable, since its very purpose is to let active agent through. The backing layer of Tapolsky is one in which the active agent “may be included.” Tapolsky col. 5, line 33. There would be no purpose in including the active agent in that layer unless it could get out and do its job, in which case the backing layer could not be impermeable to it.

Conclusion. It is hoped that the present response adequately explains why the Examiner’s rejections are not well founded. If the Examiner has any questions about this response, it is respectfully requested that she telephone the undersigned attorney.

Respectfully submitted,

By: /Flavio M. Rose/
Flavio M. Rose
Registration No. 40,791
c/o MINTZ LEVIN
5 Palo Alto Square, 6th Floor
3000 El Camino Real
Palo Alto, California 94306
(650) 251-7700 Telephone
(650) 251-7739 Facsimile
Customer Number 23980